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3733

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of GROUP I, claims 1 and 3-13 in the reply filed on December 11, 2008 is acknowledged.
2. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 11, 2008.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### *Claim Rejections - 35 USC § 103*

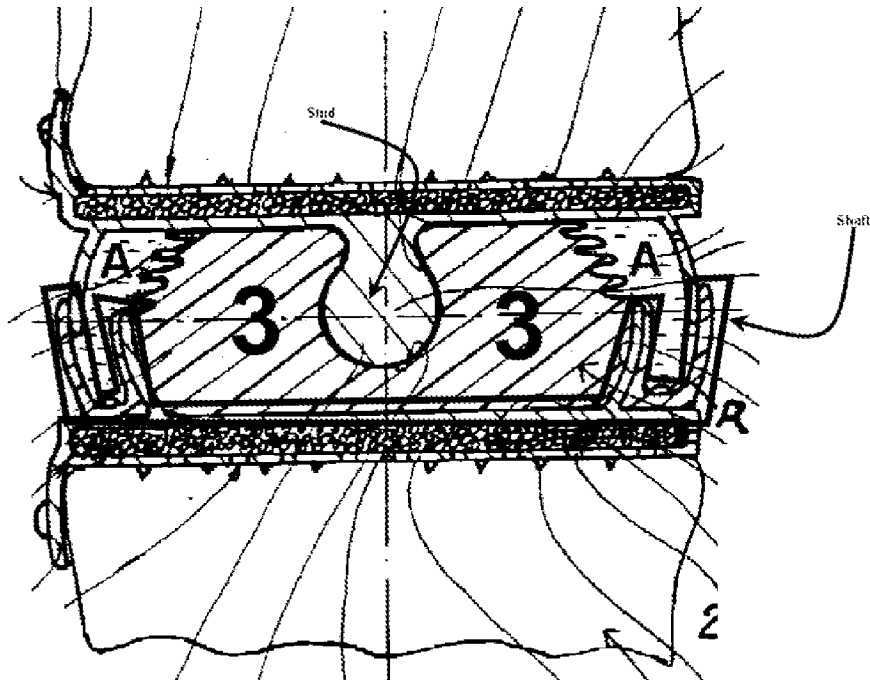
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang (U.S. Publication 2004/0193273).

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- a. Regarding claim 1, Huang discloses an intervertebral disc prosthesis (FIG 2) comprising two rigid half-shells in the form of cups or plates (1, 2) which are each intended to be fixed to one of two vertebrae adjacent to an intervertebral disc to be replaced. The two half-shells enclose a compression pad (3, A) made of at least two materials of different hardness (Paragraph [0034] – Paragraph [0038]), wherein one of the two half-shells (2) comprises, in its central zone, a shaft (24; see diagram provided) which is oriented toward the second half-shell (1), with the second half-shell comprising, in its central zone, a stud (14) whose cross section is smaller than that of the shaft and which is oriented toward the first half-shell and is engaged in the shaft of the latter, and additionally a sum of the lengths of the shaft and of the stud (14) is greater than the distance between the two half-shells (1, 2), with the compression pad (3, A) being disposed between the two half-shells, including a volume (3; see diagram provided) situated between the shaft and the stud, wherein volumes disposed outside (A) and inside (3) of the shaft, respectively, are filled with compressible materials of different hardness.
- b. Regarding claim 8, each half-shell (1, 2) comprises, on its outer face, points (121, 221) intended to promote its fixation to a vertebra (FIG 1).



6. Claims 3, 5-7 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claims 1 and 3 above.

a. Regarding claim 3, the compressible material situated outside the shaft is harder than the material situated inside the shaft (Paragraph [0034] – Paragraph [0038]).

b. Regarding claim 5, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated outside the shaft (A; see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated outside the shaft be a synthetic material of the polycarbonate urethane type, since it has been held to be within the general skill of a

worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

c. Regarding claim 6, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated inside in the shaft (3; see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated inside the shaft be a mixture of two-component silicone elastomer and of an encapsulating copolymer whose blowing agent is isobutane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

d. Regarding claim 7, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to distinctly state that the two half-shells (1, 2) are made of a titanium based alloy (Paragraph [0025]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the two half-shells be made of a titanium-based alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

e. Regarding claim 11, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud (14) and shaft (24; see diagram provided) have a trapezoidal cross section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the

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stud and shaft with a cross-section having a trapezoidal shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

f. Regarding claim 12, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud and the shaft have a non-circular cross-section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the stud and shaft with a cross-section having a non-circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding the above claims, see the figures corresponding to claims 1 and 3 above.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 3 above, and further in view of Gauchet (U.S. Patent 6,582,468).

a. Regarding claim 4, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the Shore-A hardness of the compressible material inside and outside of the shaft. Gauchet discloses an intervertebral disc implant with a compressible pad that has a Shore-A hardness of between 60 and 100 (Column 3, lines 7-8). It would have been obvious to one having ordinary skill in the art at the time

the invention was made to have the Shore-A hardness of the compressible material outside of the shaft to be between 60 and 100, and additionally the Shore-A hardness of the compressible material inside the shaft to be between 25 and 30, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Hedman et al. (U.S. Patent 4,759,769).

a. Regarding claim 9, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that there are lugs on the face of each half-shelf (1, 2). Hedman et al. disclose an intervertebral disc prosthesis that comprises lugs (46) on the inner face of two half-shells (30, 50). It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of lugs to the inner face of the half-shells, as is taught by Hedman et al. because the lugs provide the advantage of aiding in securing the half-shells to the vertebrae, which in-turn aid in attachment and implantation of the compression pad to the intervertebral disc space.

Regarding the above claim, see the figures corresponding to claim 1 and figure 1 in Hedman et al.

9. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Errico et al. (U.S. Publication 2003/0074067).



a. Regarding claim 10, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the means by which the stud (14) is fixed to the half-shell (1). Errico et al. discloses an intervertebral disc prosthesis with a stud (28) that is fixed to a half-shell (10) by being screwed into a through-hole (26). It therefore would have been obvious to one skilled in the art to modify the prosthesis taught by Huang with the fixation means of screwing the stud into the top of the half-shell, as is taught by Errico et al. because screwing the stud into the half-shell is an alternative fixation means which accomplishes the goal of attachment of the stud, while keeping the intervertebral disc prosthesis functionally and mechanically analogous to another fixation means.

b. Regarding claim 13, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose a coating on the outer surfaces of the half-shells. Errico et al. discloses an intervertebral disc prosthesis that comprises a coating on the outer surfaces of the half-shells (Paragraph [0110]) for ensuring primary osseous fixation. It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of a coating as is taught by Errico et al. because the coating provides the advantage of further aiding in bone fixation, while keeping the functional and structural features of the prosthesis analogous to that taught by Huang.

Regarding the above claims, see the figures corresponding to claim 1 and figure 1i in Errico et al.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1, 3-13 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Examiner, Art Unit 3733

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Supervisory Patent Examiner, Art Unit 3733